REMARKS/ARGUMENTS

Claims 57-63 and 65-69 are pending in the present application. Claims 57-63 and 65-69 are rejected. Applicant respectfully requests reconsideration of these claims in view of the arguments presented herein.

Rejections under 35 U.S.C. § 103(a)

Claims 57-63 and 65-69 are rejected under 35 U.S.C. § 103(a) as unpatentable over Erickson (U.S. Pat. No. 3,751,569, hereinafter referred to as "Erickson") and Miettinen *et al.* (U.S. Pat. No. 5,502,045, hereinafter referred to as "Miettinen") and Wester *et al.* (WO 99/56558, hereinafter referred to as "Wester").

Meittinen

The Office cites Miettinen as disclosing the addition 3, 6, and 13% by weight of sterol fatty acid esters to rapeseed oil, while maintaining the clarity of the rapeseed oil. Applicants respectfully disagree. Applicants can find no teaching or suggestion in Miettinen that an oil remains clear upon addition of 10% or more of a sterol ester composition. Applicants can find no teaching or suggestion in Miettinen that an oil will remain clear upon addition of more than 6% of a sterol ester composition. (Contrast Example 3 of Miettinen, which shows the addition of 3 and 6% of a sterol ester composition to a clear oil (not 13% as suggested by the Office), to Examples 2 and 5, directed to mayonnaise and margarine, respectively, showing additions at levels of 13% and 20%.) Moreover, the only times Miettinen teaches or suggests using 10% or more of a stanol ester composition in an oil, that oil is used for an application where clarity does not matter. Example 2 of Miettinen shows the addition of 13% of a stanol fatty acid ester to an oil; the oil is then used to make mayonnaise. (See, Miettinen, column 5, lines 55-60). Example 5 shows the addition of 10 and 20% stanol fatty acid ester composition to the fatty part of a margarine. (See, Miettinen, column 6, lines 39-44). Example 3 of Miettinen, the only Example specifically directed to an oil that remains clear at room temperature, teaches only the addition of

and 6% by weight, to rapeseed oil. (Miettinen, Example 3, column 6, lines 18-27).[1] Moreover, nowhere does Miettinen teach or suggest that plant sterol esters or plant stanol esters can be added to an oil at a level of greater than 6% and still maintain the clarity of the oil at room temperature. The teaching that plant stanol esters can be added at levels of up to 6% clearly does not render obvious Applicants' claimed range of 10-30% sterol ester in a clear, edible oil.

Erickson

The Office cites Erickson for disclosing a clear cooking and salad oil comprising 0.5-10% by weight of the composition of a sterol fatty acid ester, which comprises 100% of the particular monounsaturated fatty acid moiety, oleic acid. The Office states that the sterol fatty acid ester in Erickson touches or overlaps with the instant claimed range, 10-30%.

Applicant respectfully disagree. First, the 0.5-10% (free sterol equivalent) of Erickson is different from the 10-30% sterol esters claimed by Applicant. Erickson explains in his specification that "[t]he percentages of plant sterol monocarboxylic acid ester herein are calculated as if an equivalent amount of free sterol were present. This is indicated by the use of the expression '(free sterol equivalent)' after the recited percentages." (Erickson, column 1, footnote 2). Applicants, on the other hand, state in their specification that, "[a]ll percentages of sterol esters are by weight on a sterol ester basis (rather than on a free sterol basis)." (Applicants' specification, page 7, lines 11-12). As noted in Applicants' specification, the percentages claimed by Applicants, **calculated on a sterol ester basis**, are different from those of Erickson, which are **based on free sterol equivalent**. Applicants respectfully submit that the Office has not made a *prima facie* case of obviousness because it has not shown that the claimed ranges overlap with any ranges disclosed in the cited references.

Second, Applicants respectfully submit that Erickson does not enable one skilled in the art to prepare a clear cooking and salad oil with 10% by weight of the composition of a sterol fatty acid ester. Before a reference can constitute legally cognizable prior art, it must teach or

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[1] In Example 3, Miettinen states: "no permanent turbidity was observed in [the oil-stanol ester mixture] when it was stored at refrigerator temperatures," which seems to suggest that even at a level of 6% the oil did not remain clear at refrigerator temperatures but became clear once it was allowed to warm to room temperature. (Miettinen, column 6, lines 25-27).

suggest how to make what it discloses. That teaching or suggestion must be in the form of an enabling disclosure. While Erickson suggests that one may be able to make clear oils with 10% (free sterol equivalent), Erickson does not show how this is possible. The only reference in Erickson to an oil containing 10% sterol ester composition is theoretical. None of Erickson's examples show 10% sterol ester in oil. Furthermore, Erickson provides experimental results showing the solubility of different sterol esters in oil. The most soluble sterol ester discussed in Erickson, the oleate, is only soluble at a level of 7.9%. (See Erickson, column 5, Table II). None of the sterol esters listed are soluble at a level of 10%. Thus, while Erickson asserts in column 2 of his specification that oils containing up to 10% sterol oleate esters remain clear, Erickson has provided no guidance on how a sterol oleate ester can be added to an oil at 10% and remain clear. Rather, he shows experimentally that plant sterol oleate esters are **insoluble** at levels above 7.9%, thus any oil in accordance with Erickson having more than 7.9% sterol oleate ester would not be clear.

Additionally, Erickson does not provide a reasonable expectation that one can successfully prepare a clear cooking oil having 10% of a sterol fatty acid ester. In Erickson's Example I, sterol esters are added to oil at a maximum level of 8.0%; the only sterol ester added at that level being the oleate. The other sterol esters are added at levels of 2.0% and 4.0%. This can be explained by Erickson's experimental values for solubility, as listed in Table II, in column 5. Table 2 shows the solubility, in free sterol equivalent, of several different sterol esters. The solubilities are in the range from 0.1% for palmitate to 7.9% for oleate, which coincides with the addition of 8.0% oleate to oil in Example I. Moreover, in practice, and as described in Applicants' claims, sterol esters are made with a combination of fatty acids, rather than a single fatty acid, which would be expected to be less soluble overall than a sterol ester composition made from a single fatty acid such as oleate.

Erickson does not teach or suggest a clear oil having 10-30% by weight sterol esters, on a sterol ester basis, as claimed by Applicants. Furthermore, Erickson does not enable one skilled in the art to make a clear oil containing 10-30% of a sterol ester composition. Finally, there is nothing in Erickson that teaches that sterol esters can be added to a clear oil at a level of 10% with a reasonable expectation of success.

Wester

Wester does not teach or disclose an edible oil comprising more than 10% and up to 30% of a sterol fatty acid ester composition, wherein the sterol fatty acid ester composition comprises more than 50% monounsaturated fatty acid (MUFA) moieties; wherein the edible oil that contains the sterol fatty acid ester composition remains clear upon addition of the sterol fatty acid ester composition; and wherein the edible oil that contains the sterol fatty acid ester composition is free of solids at temperatures of greater than about 60°F. As noted by the Office, Wester does disclose using rapeseed oil for making stanol fatty acid esters, discussed at page 5, lines 14-17 of Wester. However, reading Wester as a whole, suggests that using high MUFA oils does not provide an adequate way to incorporate sufficient amounts of sterol esters into food products, such as oils.

First, Wester discusses Erickson on pages 2-3 (carryover paragraph), noting that Erickson "discloses the use of certain individual fatty acid esters of phytosterols added to the cooking or salad oil in **small amounts**." (Wester, page 3, lines 6-8, emphasis added). Wester then notes that Miettinen was able to add up to 20% of a sitostanol fatty acid ester could be added to food products, such as margarines or spreads. (Wester, page 3, lines 17-18). Wester then goes on to state that the problem with the prior art discussed is the production of foods with high enough contents of phytosterols to achieve the optimum effect on blood cholesterol. (Wester, page 4, lines 5-9). Wester then says that by using the invention described therein, phytostanols prepared with PUFA-enriched high PUFA oils, phytosterols could be added to oils and the like in sufficient amounts to receive optimal benefit, unlike the attempts of the prior art. (Wester, page 4, lines 10-13). Moreover, after identifying problems in the prior art, Wester found that he could overcome these problems by using PUFA-enriched high-PUFA fatty acids for preparing phytosterol compositions. So, while Wester does discuss using rapeseed oil for making stanol fatty acid esters (page 5, lines 14-16), it does not teach or suggest preparing an oil containing more than 10% of that stanol fatty acid ester composition.

Moreover, there is no teaching or suggestion in Wester that an oil containing more than 10% of a sterol ester composition comprising more than 50% monounsaturated fatty acid

(MUFA) moieties would remain clear upon addition of the sterol fatty acid ester composition; and wherein the edible oil that contains the sterol fatty acid ester composition is free of solids at temperatures of greater than about 60°F. Rather, from reading Wester, one would believe that to add a sufficient amount of phytosterol esters to receive optimal benefit, without having undesirable texturizing properties, one would have to use more than 50%, preferably more than 60%, and more preferably more than 65% PUFAs when preparing the phytostanol esters. (See, Wester, page 5, first full paragraph.)

Summary

Applicants respectfully submit that it would not have been obvious to a person of ordinary skill in the art at the time the invention was made to employ more than 10% by weight of a sterol ester composition, and to employ more than 50%, about 55-80%, or about 60-70% of MUFA moieties and less than 50% PUFA moieties in sterol fatty acid ester compositions. Neither Erickson nor Miettinen, cited as teaching the addition of sterol fatty acid esters to oils, teaches or suggests that sterol fatty acid esters can be added to oils at levels of more than 10% while maintaining the clarity of the oil. Moreover, Miettinen never teaches or suggests adding more than 6% of a sterol fatty acid ester to a clear oil, and Erickson provides experimental data showing the most soluble sterol fatty acid ester, the oleate, is only soluble in oil at a level or 7.9%. (See, Miettinen, column 6, Example 3, and Erickson, column 5, Table II.) Not only is there no teaching or suggestion that more than 10% of a sterol ester composition can be added to an oil while maintaining the clarity of that oil, from the teachings of Erickson, Miettinen, and Wester, there is no reasonable expectation of successful if one tried. Accordingly, Applicants respectfully submit that claims 57-63 and 65-69 are not obvious over the references cited.

Conclusion

In view of the remarks made herein, Applicants believe that claims 57-63 and 65-69 are in condition for allowance. A timely notice to that effect is respectfully requested.

In view of the procedural posture of this case, if the present amendment does not place this case in condition for issuance, the Examiner is urged to contact the undersigned to discuss how the case might be promptly placed in condition for allowance.

Respectfully submitted,

CALFEE, HALTER & GRISWOLD LLP

By Kristin J. Frost

Kristin J. Frost
Reg. No. 50,627
Tel.: (216) 622-8895